

### **Patient Information Leaflet**



## **ERDAFITINIB - BALVERSA®**

#### What is BALVERSA

Erdafitinib	mg (yellow), 4 mg (orange), and 5 mg (brown)

### How should you take your medicine?

Your doctor has determined your medicine dosage.

In your case, the dosage is as follows: ...... mg/day, i.e. ..... pill(s) .... mg, to be taken once a day, every day.

Swallow whole with a glass of water; do not crush, chew, or dilute the pills. Take at the same time, with or without meals.

If you forgot to take a dose, it can be taken within 12 hours. In case of vomiting, do not take an additional dose but wait for the time to take the next dose.

# Dosage - Therapy regimen

Once a day, at the same time, with or without meals	<b>6</b>		
Continuously		J3 J4 J5 J6	<b>✓ ✓</b> J28

## How to get the medicine supply?

This medication is available only from a hospital pharmacy.

Getting this medicine might take time. Be careful and order the medicine in advance.

Store this product in its original packaging, away from sources of heat and moisture.

## What else do you need to know?

#### Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor blood counts, liver function, and phosphate level in your blood), as well as clinical condition monitoring (consult an ophthalmologist every month during the first 4 months of treatment, then every trimester.)

#### Using contraceptives

This drug may harm an unborn baby. During the entire treatment and one month after its cessation, you and your partner need to use effective contraception methods (condoms combined with another method.)

#### Interactions with other medications and/or food

The occurrence of interactions between BALVERSA® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking.



Example: While taking Balversa®, avoid taking grapefruit juice, Saint John's wort, and red yeast rice.

### What are possible side effects?

The most common side effects are listed below. There might be some other side effects. For additional

information, refer to your medicine lea	aflet or seek advice from your doctor or pharmacist.
	Side effects
The most common ones	Eye problems: blurred vision, decreased vision, dryness Abnormal lab results: elevation of phosphate and creatinine levels in the blood, low hemoglobin level (anemia), abnormal liver function tests Digestive problems: constipation, nausea, diarrhea, abdominal pain, inflammation inside mouth (stomatitis), loss of appetite, problems or loss of taste (or smell), weight gain Nails: paronychia (nail infection), deformity, change in color, nail peeling Pain: in muscles (myalgia), in joints (arthralgia) Skin problems: skin dryness, inflammation of the palms of the hands, soles of the feet, and areas of friction General problems: fatigue, loss of appetite, loss of weight
	When to alert the medical team?
Tell medical personnel if the following conditions are present and in the absence of specific medical advice	Eye problems Pain in the eyes, watering eyes or redness, blurred vision, or light sensitivity Digestive problems Significant and/or rapid weight loss Very frequent diarrhea, bowel movement over 4 times a day Pain inside the mouth or ulcers that prevent normal eating Severe abdominal pain Inability to drink for 24 hours and/or eat for about 48 hours Bowel movements fewer than 3 times a week Muscle problems Unusual and inexplicable pain in muscles
	How to prevent side effects?
Oral hygiene	Use a soft toothbrush; use oral rinses containing baking soda.  Avoid oral rinses that contain menthol or alcohol.
Nails	Avoid fingernail and toenail injuries. Avoid using nail polishes, except protective polish specifically recommended to you by your medical team.  Opt for straight shaped nails and don't cut your nails too short.
Skin care	On hands and feet: Apply moisturizing cream or lotion and/or healing cream on hands and feet (without rubbing hard).  Avoid exposing hands and feet to heat (hot water). Avoid activities that cause rubbing or injury. Avoid wearing overly tight clothing, socks, or shoes.  Body: For washing, opt for a mild soap and moisturizer, pat skin dry. Avoid using any irritating products.
Eyes	Avoid wearing contact lenses. Use artificial tears regularly (ideally every 2 hours during periods of activity.) Avoid driving in low light.
Fatigue	Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walking, work in the garden, swimming, biking, sports  Alternate periods of activity and rest.
	How to adapt your diet?
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes.  Limit consumption of fatty, fried, and spicy foods.



Revision date: March 19, 2024

Constipation	Opt for a high fiber diet. Drink plenty of water.	
Diarrhea	Opt for a low fiber diet. It is preferable to consume starchy products, carrots, and bananas.  Avoid using raw fruit and vegetables, dairy products, coffee, or alcohol.  Drink plenty of water.	
Taste perception problem	Opt for several small meals of warm and cold food per day.  Avoid using metal kitchen utensils.	
Inflammation inside mouth (ulcers)	Avoid sour, sticky, or very salty foods.	
Increase of phosphate levels in blood	Control phosphate intake to 600–800 mg/day (main dietary sources of phosphorus include: especially milk, chocolate, eggs, nuts and seeds, fish, edible offals (mainly liver), meat, and soft drinks.	